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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,126	08/23/2006	Yehudit Natan	27586U	5429

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THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	PAPER NUMBER
1654	
MAIL DATE	DELIVERY MODE
07/22/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,126	NATAN ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *54-63 and 66-99* is/are pending in the application.

4a) Of the above claim(s) *67-91 and 93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *54-60,62,63,92 and 94-99* is/are rejected.

7)☒ Claim(s) *61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 August 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 28, 2010 has been entered.

2. Applicant's election with traverse of Group I, claims 54-72 and 86-92, in the reply filed on April 6, 2009 is acknowledged. The requirement is still deemed proper and is therefore made FINAL.

Claims 73-85 and 93 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on April 6, 2009.

Applicant's election without traverse of the species hematopoietic stem cells in the reply filed on April 6, 2009 is acknowledged.

Claims 67-72 and 86-91 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on April 6, 2009.

3. The amendment filed June 28, 2010 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment inserting the claim for priority as the first paragraph contains new matter because of its incorporation by reference to the content

of the two provisional applications. The application as originally filed did not include an incorporation by reference statement, and the insertion of such a statement after the filing date of the application is new matter. See MPEP 201.11(III)(F), last paragraph. Applicant is required to cancel the new matter in the reply to this Office Action.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 54-56, 58-60, 62, 63, 66, and 92 are rejected under 35 U.S.C. 103(a) as being obvious over Mann et al (U.S. Patent Application Publication 2003/0059338). Mann et al teach sterilization of biological materials including stem cells, red blood cells, white blood cells, and monocytes, in which the biological materials are combined with a flavonoid/flavonol stabilizer including epigallocatechin gallate and an optional additional stabilizer including trehalose, and wherein the residual solvent content of the biological material is reduced prior to irradiation, such as by lyophilization. The biological materials, including the lyophilized biological materials, are stored under vacuum or in an inert atmosphere prior to irradiation. See, e.g., paragraphs [0027], [0031], [0036], [0037], [0058], [0059], [0078], and [0081]. Mann et al do not teach the specific combination of subjecting biological materials which are cells to lyophilization, storage, and irradiation. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to subject the biological materials including stem cells, red blood cells, white blood cells, and monocytes of Mann et al to lyophilization, storage, and irradiation in the presence of stabilizers including epigallocatechin gallate and trehalose because Mann et al teach the desirability of sterilizing such biological materials, and teach the utility of combinations of treatments, i.e. use of a stabilizer, lyophilization, and storage

under vacuum prior to irradiation, in order to sterilize the biological materials. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine the stabilizers of Mann et al in the form of a solution with the biological material to be sterilized, because it is easier to mix ingredients in solution form, because the stabilizer solvent would be removed by the lyophilization step and thus would not be expected to interfere with the final product, and because use of a solvent for the stabilizers would not appear to result in any different properties for the lyophilized mixture.

6. Claim 57 is rejected under 35 U.S.C. 103(a) as being obvious over Mann et al (U.S. Patent Application Publication 2003/0059338) as applied against claims 54-56, 58-60, 62, 63, 66, and 92 above, and further in view of Burdick et al (U.S. Patent Application Publication 2003/0083270). Mann et al teach a stabilizer which is epigallocatechin gallate, but do not teach epigallocatechin gallate which is derived from green tea extract. Burdick et al teach that epigallocatechin gallate is a known component of green tea extract which can be isolated and produced from green tea extract by chromatography. See, e.g., the abstract. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use epigallocatechin gallate derived from green tea extract as the source of Mann et al's epigallocatechin gallate, because Mann et al teach the use of epigallocatechin gallate, because Burdick et al teach that epigallocatechin gallate is found in and can be isolated and produced from green tea extract, because the source of a particular compound would not have been expected to affect the compound's activities, and because it is prima facie obvious to use the product of one process as the source of a reactant for another process. In re Kamlet, 88 USPQ 106 (CCPA 1950).

7. Claims 94 and 97 are rejected under 35 U.S.C. 103(a) as being obvious in view of Mann et al (U.S. Patent Application Publication 2003/0059338) as applied against claims 54-56, 58-60, 62, 63, 66, and 92 above, and further in view of the European Patent Application 1,057,405. Mann et al do not teach a % viability for their lyophilized cells. The European Patent Application '405 teaches that cryopreservation of normal and useful cells has a survival ratio of about 10 to 30%. See paragraph [0002]. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to perform the lyophilization of Mann et al and to achieve a % viability of up to about 30%, because it is reasonable to assume that Mann et al is able to achieve % viabilities about equal to that achieved by other prior art processes, and because Mann et al teach the cryoprotectants actually used by Applicants to achieve their % viabilities. This rejection could be overcome, e.g., by submission of evidence that Mann et al is not able to achieve the % viabilities achieve by the prior art and/or claimed by Applicants.

8. Claims 54, 58-60, 63, 66, 92, and 94-99 are rejected under 35 U.S.C. 103(a) as being obvious over Nussinovitch et al (U.S. Patent No. 7,422,737) in view of Keller (U.S. Patent Application Publication 2003/0047515). Nussinovitch et al teach producing freeze-dried hydrocolloid beads comprising viable microorganisms, wherein viability of 50-95% over a period of 12 to 36 months is obtained after storage at temperatures of at or below -18°C. Preferred microorganisms include bacteria and fungi. Lignin is added as a nutrient to the hydrocolloid solution prior to freeze-drying. There is no disclosure of the addition of DMSO. Freeze-drying can be at a temperature below or at -18°C. See, e.g., the Abstract; column 3, lines 36-50; column 4, lines 42-52; column 8, lines 56-59; column 9, lines 1-11; and claims 12, 17, 25, and 27. Keller teaches that lignins are polyphenols (see paragraph [0022]) and therefore shows

that Nussinovitch meets Applicants' claim requirement for addition of a polyphenol. Nussinovitch et al do not teach adding the lignins in the form of a solution. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to combine the lignin of Nussinovitch et al in the form of a solution with the hydrocolloid solution and microorganisms to be subjected to freeze drying, because it is easier to mix ingredients in solution form, because the lignin solvent would be removed by the lyophilization step and thus would not be expected to interfere with the final product, and because use of a solvent for the lignin would not appear to result in any different properties for the lyophilized mixture. With respect to instant claims 58, 92, and 97-99, Nussinovitch et al do not require the use of glycerol, although Nussinivitch et al prefer its use in order to increase viability of the freeze-dried microorganisms. See, e.g., column 3, lines 11-23. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to omit the glycerol from the freeze-dried hydrocolloid beads of Nussinovitch et al, because Nussinovitch et al do not require the use of glycerol, and because it is prima facie obvious to omit a component with only the expected loss of the component's function. See MPEP 2144.04(II)(A). Omission of the glycerol from Nussinovitch et al's freeze-dried hydrocolloid beads would still have been expected to result in a cell viability which satisfies the requirements of instant claims 97-99, because the percentages recited in instant claims 97-99 are significantly below the maximum percentages achieved by Nussinovitch et al, and because instant claims 97-99 do not recite any storing conditions or times and thus would have been expected to be achievable by Nussinovitch at least for short storage times.

9. Applicant's arguments filed June 28, 2010 have been fully considered but they are not persuasive.

The new matter objection under 35 U.S.C. 132, originally directed towards the amendment filed October 26, 2009, is maintained towards the amended specification paragraph contained in the amendment filed June 28, 2010. This new matter objection was separate from the objection based upon the incorrect provisional application filing date. This new matter objection is directed towards the presence of the incorporation by reference statement contained in the paragraph, which incorporation by reference statement was not present in the application as originally filed.

The obviousness rejection over Mann et al (U.S. Patent Application Publication 2003/0059338) is maintained. Applicants' arguments duplicate those filed October 26, 2009, and the examiner maintains his position for the reasons set forth in his response to the earlier filed arguments. See the Office action mailed January 26, 2010, pages 8-9. In addition to Mann et al's disclosure, e.g., at paragraphs [0063]-[0069], [0080], and [0081], as to how to effect sterilization while protecting the desired biological material which is to be sterilized, the examiner hereby cites Kent (U.S. Patent No. 6,171,549 - see, e.g., column 3, lines 3-14; Table 1; and Example 11) and Horowitz et al (U.S. Patent No. 5,981,163 - see, e.g., claims 1 and 8-13) to show that it is known in the prior art how to sterilize biological compositions comprising desired cells using radiation without significantly harming the desired cells. Applicants' assertion that Mann et al are non-enabled with respect to non-proteinaceous materials is unsupported by evidence or by scientific argument.

10. Dingwall (U.S. Patent No. 3,548,051) is cited as art of interest, teaching the treatment of erythrocytes with formalin and tannin and then freeze-drying the treated erythrocytes. Note that while treatment of the erythrocytes with formalin may be expected to end metabolism of the erythrocytes, only dependent claims 94-96 require that cell viability be maintained. However, currently Dingwall is deemed to be duplicative of the references applied above.

11. Claim 61 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
July 22, 2010